

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims:

1-40. (Cancelled)

41. (Currently Amended) A drug delivery system, comprising:

a plurality of nanoparticles or microparticles of a poorly soluble drug dispersed in a polymeric hydrophilic bead, the nanoparticles or microparticle being in an amorphous, non-crystalline state which enhances dissolution of the poorly soluble drug upon administration; and

a disintegrate mixed with the bead.

42. (Currently Amended) [[A]] The drug delivery system according to claim Claim 41, wherein the polymeric bead consists essentially of a single species of hydrophilic polymer.

43. (Currently Amended) [[A]] The drug delivery system according to claim Claim 42, wherein the polymeric bead is selected from[:]: the group consisting of a polysaccharide polymer, a synthetic polymer[,]] and a protein.

44. (Currently Amended) [[A]] The drug delivery system according to claim Claim 41, wherein the poorly soluble drug is selected from[:] the group consisting of simvastatin, statins, risperidone, carvedilol, carbamazepine, oxcarbazepine, zaleplon, galantamine, an anti Alzheimers drug, an anti epileptic drug, an anti parkinsonian drug[.,]] and other drugs used for CNS indications.

45. (Cancelled)

46. (Currently Amended) [[A]] The drug delivery system according to claim Claim 41, further comprising a crosslinker.

47. (Currently Amended) [[A]] The drug delivery system according to claim Claim 46 41, wherein the crosslinker is a multivalent cation.

48. (Currently Amended) A drug delivery system according to claim Claim 47 41, wherein the disintegrate is capable of breaking the crosslinking by replacing or chelation of the crosslinking multivalent cation.

49. (Currently Amended) [[A]] The drug delivery system according to claim Claim 41, wherein the disintegrate is a calcium chelator.

50. (Currently Amended) [[A]] The drug delivery system according to claim Claim 41, wherein the beads are gelatin beads.

51. (Currently Amended) A drug delivery system, comprising:
an active ingredient dispersed within a crosslinked polymeric bead, ~~wherein the crosslinking is the crosslinked polymeric bead being crosslinked~~ by a cation selected from the group consisting of calcium, iron, magnesium and copper, and
~~wherein the drug delivery system further comprises as a disintegrant comprising~~
a chelator of calcium.

52. (Currently Amended) [[A]] The drug delivery system according to claim Claim 51, wherein the active ingredient is a poorly soluble drug.

53. (Currently Amended) [[A]] The drug delivery system according to claim Claim 52, wherein the poorly soluble drug is in the form of nanoparticles.

54. (Withdrawn) A method for producing the drug delivery system of Claim 41, comprising:
(i) providing poorly water soluble drug dissolved in organic volatile solvent or mixture of organic volatile solvent with co-solvent that is either miscible or immiscible with water, optionally in the presence of at least one surfactant;
(ii) mixing the drug containing solvent with an aqueous phase comprising at least one surfactant and optionally co-solvent and other emulsification aids at such conditions in which an oil-in-water nanoemulsion or microemulsion is formed;

- (iii) mixing the oil-in-water nanoemulsion or microemulsion with water-soluble bead forming polymers to produce a continuous phase of the emulsion which is capable of forming a bead;
- (iv) providing conditions enabling bead formation from the continuous phase of (iii) containing nano- microemulsion droplets;
- (v) optionally evaporating the volatile organic solvent and the water, thereby obtaining dry beads containing in the polymeric bead dispersed nanoparticles of poorly water soluble drugs.

55. (Withdrawn) A method according to Claim 54, wherein the mixing of the poorly water soluble drug in an organic solvent occurs in the presence of at least one surfactant.

56. (Withdrawn) A method according to Claim 54, wherein the drug containing solvent is mixed within an aqueous phase containing a surfactant, the aqueous phase further containing a co-surfactant and/or co-solvent, and/or electrolytes.

57. (Withdrawn) A method according to Claim 54, wherein the nanoemulsion is prepared by homogenization by a high pressure homogenizer or by a phase inversion method.

58. (Withdrawn) A method according to Claim 54, wherein the microemulsion is formed spontaneously by proper selection of the surfactants, solvent, co-solvent and co-surfactants.
59. (Withdrawn) A method according to Claim 54, wherein at step (iv) the beads are incubated under suitable conditions and for suitable periods of time, with external crosslinking agents.
60. (Withdrawn) A method according to Claim 59, wherein the polymer is an anionic polymer and external crosslinkers are multivalent cations selected from calcium, magnesium, copper, iron, barium and salts of these cations.
61. (Withdrawn) A method according to Claim 59, wherein the polymer is a cation polymer and external crosslinkers are polyvalent anions selected from polyanions or sodium tripolyphosphate.
62. (Withdrawn) A method for producing a pharmaceutical composition comprising packing the beads obtained in Claim 54 within a capsule or tablet.
63. (Withdrawn) A method according to Claim 62, wherein disintegrator is added to the dry beads prior to packing the beads in a capsule or tablet.

64. (Withdrawn) A method according to Claim 63, wherein the disintegrator is selected from chelators and molecules capable of replacing the crosslinking ions.

65. (New) The drug delivery system according to claim 41, wherein the poorly soluble drug is selected from the group consisting of simvastatine, statines, risperidone, carvedilol, carbamazepine, oxcarbazepine, zaleplon and galantamine.